JUSTIN T. BERGER (SBN 250346)
jberger@cpmlegal.com
MALLORY A. BARR (SBN 317231)
mbarr@cpmlegal.com
COTCHETT, PITRE & McCARTHY, LLP
San Francisco Airport Office Center
840 Malcolm Road
Burlingame, CA 94010
Telephone: (650) 697-6000
Facsimile: (650) 697-0577

Attorneys for Relator STF, LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA *ex rel.* STF, LLC, an organization; STATE OF CALIFORNIA; *ex rel.* STF, LLC, an organization, Plaintiffs, v. VIBRANT AMERICA, LLC, a Delaware limited liability company, Defendants.	CASE NO. 3:16-cv-02487-JCS **RELATOR STF, LLC'S OPPOSITION TO DEFENDANT VIBRANT AMERICA LLC'S MOTION TO DISMISS RELATOR'S COMPLAINT** Date: July 24, 2020 Time: 9:30 a.m. Ctrm: F Judge: Hon. Joseph C. Spero

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I. INTRODUCTION AND STATEMENT OF ISSUES TO BE DECIDED

Relator STF, LLC's Complaint details two distinct healthcare kickback schemes perpetrated by Defendant Vibrant America, Inc.: (1) payment of illegal and inflated "packaging" fees to physicians and their staff; and (2) capping and waiving patient copayments and deductibles to induce the continued ordering of expensive laboratory tests.

Last month, in a parallel case brought by Relator against another Northern California laboratory engaged in the same schemes, Magistrate Judge Hixson rejected the same arguments Defendant makes here, and held: (1) Relator did not need to prove that the laboratory defendants' $15 packaging fees were greater than fair market value to adequately plead they were an inducement in violation of the Anti-Kickback Statutes (AKS) and False Claims Act (FCA); and (2) Relator's allegations of defendants trying to disguise their processing fee and patient copayment waiver schemes adequately alleged facts supporting a plausible inference of their scienter. *United States v. Crescendo Biosciences, Inc.*, No. 16-CV-02043-TSH, 2020 WL 2614959, at *7-*9 (N.D. Cal. May 23, 2020).

Magistrate Judge Hixson's decision is not the first to address similar schemes in the medical laboratory industry. Defendant's schemes have been the subject of multiple, successful False Claims Act lawsuits against other medical laboratories over the past decade. For example: In 2015, Health Diagnostics Laboratory (HDL) and Singulex agreed to pay $48.5 million to the United States to settle nearly identical allegations in a case brought by multiple whistleblowers.[1] In 2018, DOJ won a jury trial against HDL's former CEO and the heads of HDL's third-party sales force.[2] And most recently, in November 2019, Boston Heart Diagnostics Corp. (Boston Heart) agreed to pay $26.67 million to settle similar claims.[3]

[1] *United States v. Blue Wave Healthcare Consultants, et al.*, No. 9:14-230-RMG (D.S.C. 2018), Settlement Agreements, Dkt. Nos. 588-1 and 588-2.
[2] *U.S. v. Blue Wave Healthcare Consultants, et al.*, No. 9:14-230-RMG (D.S.C. 2018), Verdict Form, Dkt. No. 870.
[3] Press Release, U.S. Dep't of Justice, Laboratory to Pay $26.67 Million to Settle False Claims Act Allegations of Illegal Inducements to Referring Physicians (Nov. 26, 2019) *available at* https://www.justice.gov/opa/pr/laboratory-pay-2667-million-settle-false-claims-act-allegations-illegal-inducements-referring (last accessed April 28, 2020). One of the members of Relator STF, LLC is Chris Riedel, a former laboratory owner and executive. Mr. Riedel was a whistleblower—often one of several—in all of these cases. Defendant spends a great amount of energy impugning Mr. Riedel for his role as a successful whistleblower. As discussed below in Section G, rather than being impugned, Mr. Riedel should be congratulated for his role in protecting the public fisc.

In addition to returning tens of millions of dollars to taxpayers, these cases generated caselaw that is directly on point—caselaw Defendant conspicuously omits from its Motion to Dismiss. For example, in the HDL cases, the District Court rejected the same arguments Defendant makes here, ruling that: (1) defendants' characterization of their kickbacks as "packaging and handling" fees instead of "draw" fees was indicative of defendants' knowledge; and (2) capping or waiving patients' copayments is illegal remuneration implicating the AKS, and the relator need only allege that one purpose of such waivers was to induce referrals. *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 499-500 (D.S.C. 2016) ("*Berkeley Heartlab I*"). Similarly, in the Boston Heart case, the District Court held: (1) allegations that the laboratory defendant paid packaging fees of $15 to $25—well in excess of the $3 authorized by the Medicare Fee Schedule—implicated the AKS and FCA; and (2) waiver of patient copayments and deductibles in exchange for referrals sufficiently alleged illicit remuneration in violation of the AKS and FCA. *U.S. ex rel. Riedel v. Boston Heart Diagnostics, Corp.,* 332 F. Supp. 3d 48, 78-79 (D.D.C. 2018).

Defendant ignores these rulings and makes the same flawed arguments that have already been rejected by Magistrate Judge Hixson and other District Court decisions. In sum, Defendant's arguments on the issues to be decided fail for the following reasons:

(1) It is well established that paying "packaging and handling" and "collection" fees and capping and waiving patient copayments are inducements that violate the AKS and therefore result in false claims.

(2) The Complaint need only allege "with particularity the circumstances constituting fraud." While this entails alleging generally "the who, what, when, where, and how of the misconduct charged," it "does not require absolute particularity." *U.S. ex rel. Swoben v. United Healthcare Ins. Co*., 848 F.3d 1161, 1180 (9th Cir. 2016). Relator's allegations in the Complaint meet the standard and level of detail the Ninth Circuit found sufficient in *Swoben*. *See id.* The Complaint alleges schemes perpetrated by Defendant as part of its regular business practices and identifies, among other details, (a) Defendant's specific contracts for illegal "packaging and handling" and "collection" fees and how the scheme is carried out, and (b) a specific conversation where Defendant's employee pitched Vibrant's illegal capping and waiving of patients' copayments to a referring physician.

(3) Relator's Complaint adequately alleges materiality, as kickbacks are always material to the payment of healthcare claims.

(4) Relator's Complaint adequately alleges Defendant's *scienter* for both schemes because Defendant disguised its illicit schemes, knowing they were kickbacks, and OIG guidance and lawsuits have put the entire industry on notice of the illegality of these schemes.

(5) Relator's Complaint adequately states a claim under the California False Claims Act (CFCA), for the same reasons.

(6) Relator is an "interested party" under the California Insurance Fraud Prevention Act (CIFPA) with standing to bring its adequately plead claims.

Accordingly, Relator respectfully requests the Court deny Defendant's Motion to Dismiss in its entirety. In the alternative, Relator requests leave to amend.

II. FACTUAL ALLEGATIONS

Defendant Vibrant is a laboratory company based in San Carlos. Compl. ¶ 11. Briefly summarized, the Complaint alleges two categories of kickbacks Defendant provides to induce physicians to refer business: (1) "processing and handling" (P&H) or "collection" fees paid directly or indirectly to physicians, their staff, or family through sham phlebotomist agreements (processing fee scheme); and (2) capping or completely waiving patients' copayments and deductibles (waiver scheme). Each constitutes conduct prohibited by the AKS, and, consequently, violations of the FCA. The same conduct also violates the CFCA and CIFPA.

A. Defendant paid physicians prohibited "processing and handling" and "collection" fees to induce referrals.

In its first illegal kickback scheme, Vibrant pays unlawful "processing and handling" and "collection" fees that far exceeded the fair market value for such services. Compl. ¶¶ 32, 39. Vibrant's sales representatives contact physicians' offices and offer to make the physicians' family or staff members "independent contractors" of Vibrant. *Id.* at ¶¶ 32, 33. Vibrant then executes Phlebotomist Consulting Agreements (PCAs) and Phlebotomist Service Agreements (PSAs) with the physicians' family or staff members. *Id.* at ¶¶ 36, 37, Exs. A and B.

Under the terms of the PSAs, the physicians' family or staff members are paid $15 per hour to do routine blood draw and send samples to Vibrant for analysis. *Id.* at Ex. A. Additionally, under the terms of the PSAs, Vibrant pays the physicians' family or staff members $15 per patient blood sample collected and $15 per sample shipped, even though the fair market value of the cost of drawing blood is a fraction of that rate. *Id.* at ¶¶ 32, 33, 39; Ex. B at p. 1. Vibrant pays these fees regardless of who actually performs the blood draw. *Id.* at ¶¶ 33, 38. At the end of each month, the staff or family member submits a "monthly log list" to Vibrant. *Id.* at Ex. B, p. 1. Vibrant then sends the staff or family member a check for those collections. *E.g., id.* at Ex. C. This illegal arrangement allows the physicians or their medical staff to supplement their income by ordering more tests through Vibrant. *Id.* at ¶ 34.

Medicare reimburses simple blood draws—also known as venipunctures—at $3. *Id.* at ¶ 39. Yet, Defendant pays $15 for these routine blood draws in order to induce physicians to refer more testing to Defendant. *Id.* at ¶¶ 39, 41. Vibrant submits these claims tainted by kickbacks to Medicare, Medi-Cal and private insurers, in violation of the FCA, CFCA, and CIFPA. *Id.* at ¶¶ 40, 42, 53.

B. Defendant capped or waived patient copayments or deductibles to induce physicians' referrals of business.

In Defendant's second illegal kickback scheme, it caps and then waives patients' copayment or deductible responsibility for their testing in a *quid pro quo* arrangement inducing the physician referring additional business to Defendant. *See* Compl. ¶ 45.

Generally, patients receiving medical treatment must pay a copayment or deductible. When a patient has not met their deductible, they are responsible for paying for the cost of testing. These tests, including Vibrant's Cardiovascular and Women's Health panels, can cost patients hundreds of dollars in copayments and deductibles. *Id.* at ¶¶ 46-47.

Recognizing the value of providing free testing for physicians' patients, Vibrant tells referring physicians it will cap patients' copayment or deductible responsibility at no more than $25 for their tests. *Id.* at ¶ 45. Vibrant makes this promise regardless of the amount the patient would otherwise owe. *Id.* Additionally, if a patient does not pay this nominal amount, Vibrant assures physicians it will not make efforts to collect. *Id.* Vibrant even instructs physicians to tell their patients to ignore

bills. *Id*. In exchange for Vibrant providing this benefit to physicians' offices, the physician is expected to send Vibrant all of their business, especially business reimbursed by Medicare and Medi-Cal. *See*, *id.* at ¶ 49.

Defendant knows this is prohibited by the AKS and FCA, as has been made clear in opinion letters from the Office of the Inspector General (OIG) and successful litigation against other laboratories over the same conduct. *See*, Compl. ¶ 43. Defendant's efforts to conceal its conduct, as the government regulators caught up to the fraud occurring throughout the industry, demonstrates a knowing and willful effort to violate the AKS and FCA. *See, e.g.*, *id.* at ¶ 48. Because Defendant submits these tainted claims—in addition to Medicare—to Medi-Cal and private insurers, Defendant's schemes are also prohibited under CFCA and CIFPA. *Id*. at ¶¶ 50, 53.

III. LEGAL STANDARD

A. The False Claims Act and California False Claims Act must be interpreted liberally and broadly construed.

Courts and Congress have repeatedly mandated the False Claims Act (FCA) be interpreted liberally. As stated by the Ninth Circuit: "according to Congress the FCA should be broadly construed." *U.S. ex rel. Hooper v. Lockheed Martin Corp*., 688 F.3d 1037, 1048 (9th Cir. 2012). The goal of the FCA generally is to ensure integrity in government contracting and the statutes embody "the maxim that [people] must turn square corners when they deal with the Government." *U.S. ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 302 (6th Cir. 1989).

Similarly, the California False Claims Act (CFCA) also must be "liberally construed and applied to promote the public interest." Cal. Gov. Code § 12655(c). "[I]n as much as the False Claims Act obviously is designed to prevent fraud on the public treasury, it plainly should be given the broadest possible construction consistent with that purpose." *City of Pomona v. Super. Ct.* (Cal. Ct. App. 2001) 89 Cal. App. 4th 793, 801-02 (internal quotations omitted). The CFCA "must be construed broadly so as to give the widest possible coverage and effect to the prohibitions and remedies it provides." *Id.* (citation omitted). The statute is "intended to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Id*. at 802, *citing United States v. Neifert-White Co*. (1968) 390 U.S. 228, 232.

B. The Ninth Circuit applies a flexible pleading standard for False Claims Act complaints under Rules 12 and 9 of the Federal Rules of Civil Procedure.

"Rule 12(b)(6) is read in conjunction with Rule 8(a), which requires only a short and plain statement of the claim showing that the pleader is entitled to relief." *Peel v. Brooksamerica Mortgage Corp*., 788 F. Supp. 2d 1149, 1157 (C.D. Cal. 2011). A complaint need only allege "enough facts to state a claim to relief that is plausible on its face," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007), or allege sufficient facts to "raise a right to relief above the speculative level," *id*. at 555. The Court must accept as true all allegations of material facts alleged in the complaint and must draw all inferences in the light most favorable to the non-moving party. *Moyo v. Gomez*, 32 F.3d 1382, 1384 (9th Cir. 1994).

"The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Ashcroft v. Iqbal*, 556 U.S. 672, 678 (2009) (quoting *Twombly*). "If there are two alternative explanations, one advanced by defendant and the other advanced by plaintiff, both of which are plausible, plaintiff's complaint survives a motion to dismiss under Rule 12(b)(6)." *Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011), *cert. denied*, 132 S. Ct. 2101 (2012). Accordingly, a complaint "need not rule out all possible innocent explanations." *In re Auto. Parts Antitrust Litig.*, No. 12-MD-02311, 2014 WL 840272, at *6 (E.D. Mich. Mar. 4, 2014).

The Ninth Circuit further elaborated the proper standard by which to measure a False Claims Act complaint in *U.S. ex rel. Swoben v. United Healthcare Ins. Co*., 848 F.3d 1161, 1180 (9th Cir. 2016): "[p]erhaps the most basic consideration for a federal court in making a judgment as to the sufficiency of a pleading for purposes of Rule 9(b) ... is the determination of how much detail is necessary to give adequate notice to an adverse party and enable that party to prepare a responsive pleading." Moreover, "[b]y requiring some factual basis for the claims, the rule protects against false or unsubstantiated charges." *Id*. "Because this standard 'does not require absolute particularity or a recital of the evidence,' … , a complaint need not allege 'a precise time frame,' 'describe in detail a single specific transaction' or identify the 'precise method' used to carry out the fraud, … . The complaint also need not 'identify representative examples of false claims to support every allegation.'" *Id*. (citations omitted).

C. Violations of the AKS give rise to False Claims Act violations.

The Anti-Kickback Statutes make improper remuneration in the context of federal health care programs illegal. Among other things, the statute makes it a felony to "knowingly and willfully" offer, pay, solicit, or receive remuneration in exchange for making, arranging for, or recommending a referral "for an item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b).

Remuneration includes "any kickback, bribe or rebate," and broadly applies to anything of value provided "directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(1), (2). In 2010, Congress adopted the view of a majority of circuit courts when it clarified that "a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim" under the FCA. 42 U.S.C. § 1320a-7b(g); *accord U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F. 3d 295, 313-14 (3d Cir. 2011) (reaching this conclusion as to claims predating Congress's 2010 amendment); *U.S. ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 52 (D. Mass. 2011) ("The amendment's legislative history, however, evinces Congress' intent to clarify, not alter, existing law that claims for payment made pursuant to illegal kickbacks are false under the False Claims Act.").

IV. ARGUMENT

A. The Complaint adequately alleges Defendant's kickback schemes violate the AKS.

Defendant first argues that the packaging fees and patient copayment waivers it provides do not constitute "remuneration" for purposes of the anti-kickback laws. The plain language of the statutes, however, is to the contrary. The federal AKS defines remuneration in sweeping terms, as including "any kickback, bribe, or rebate[,] directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C.A. § 1320a-7b(b)(1). A violation of the AKS requires only that Relator allege "one purpose" of the payment is to induce referrals. *See United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989). As described below, Relator's Complaint sufficiently alleges violations of the AKS.

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1. Defendant's "packaging and handling" and "collection" fees are remuneration that violate the AKS.

In an effort to justify its practices, Vibrant makes factual arguments that its excessive $15 "processing and handling" and "collection" fees reflect fair market value. Vibrant's argument is wrong on the facts and the law.

Defendant improperly conflates two concepts: fair market value and inducements. Magistrate Judge Hixson considered and appropriately rejected identical arguments in the *Crescendo* case, explaining: "the AKS can be implicated *whenever* a clinical laboratory pays a physician for services, even if payment doesn't exceed fair market value for the service." *Crescendo*, 2020 WL 2614959 at *7 (citing 2014 OIG Special Fraud Alert; emphasis in original). Indeed, no case or statute cited by Defendant *requires* that a payment exceed fair market value in order to violate the AKS. Where the payment exceeds fair market value, as is the case here, there is an inference that it was done with the intent to induce referrals. OIG Special Fraud Alert: Laboratory Payments to Referring Physicians (Issued June 2014)[4] ("2014 OIG Special Fraud Alert"). But inducements can occur even if the payment is equal to fair market value. *See U.S. ex rel. Bartlett v. Ascroft,* 39 F. Supp. 3d 654, 677 (W.D. Pa. 2014), *quoting* OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858, 4864 (Jan. 31, 2005) ("Importantly, under the anti-kickback statue, neither a legitimate business purpose for the arrangement, nor a fair market value payment, will legitimize a payment if there is also an illegal purpose (i.e., inducing Federal health care program business)."); *see also, e.g.*, OIG Advisory Opinion No. 08-06;[5] OIG Opinion Letter, April 26, 2000;[6] OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Issued October 1994), reprinted at 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994);[7] 2014 OIG Special Fraud Alert; *United States v. Bay State*

[4] *Available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf (last accessed April 30, 2020) (explaining that if one purpose of the remuneration is to induce or reward referrals of business, then payments to physicians for laboratory samples are kickbacks "regardless of whether the payment is fair market value").

[5] *Available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-06.pdf (last accessed April 30, 2020).

[6] *Available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/lab.htm (last accessed April 30, 2020).

[7] *Available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html (last accessed April 30, 2020).

Ambulance and Hosp. Rental Serv., Inc., 874 F. 2d 20, 29 (1st Cir. 1989) ("Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.").

Here, the Complaint alleges both that the payments are inducements (Compl. ¶¶ 32, 39) and that they exceed fair market value. *See id*. ¶¶ 39, 41. In response, Defendant first argues that its $15 fees are for packaging services that go far beyond what is covered by the $3 Medicare "draw" fee. To begin with, that is a factual dispute not appropriate for this motion. Moreover, Vibrant is wrong: processing and packaging services are widely considered by healthcare payers, including Medicare, to be included in the payments physicians receive for the patient visit.[8] In other words, whatever the fair market value of a physician office's time for handling and packaging a blood specimen, the physician is already reimbursed for that time. Accordingly, Vibrant's payments cannot be considered anything other than a bribe. Finally, even if packaging and handling had some legitimate fair market value beyond what physician offices already receive, it would not equal four times the value of the blood drawing service set by Medicare ($3).[9]

[8] The pertinent CPT code is 99000, which covers "[h]andling and/or conveyance of specimen for transfer from the physician's office to a laboratory." Medicare does not separately reimburse CPT code 99000, but instead lists it as a "Bundled Code," meaning "payment for them is subsumed by the payment for the services to which they are incident." *See* Medicare Part B 2020 National Physician Fee Schedule Relative Value File, available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files; "HOW TO USE THE SEARCHABLE MEDICARE PHYSICIAN FEE SCHEDULE (MPFS)," *available at* https://www.cms.gov/apps/physician-fee-schedule/help/How_to_MPFS_Booklet_ICN901344.pdf.

[9] Moreover, under Defendant's own contracts, "independent contractor" phlebotomists can be paid: (1) $15 per hour under the PSCs (Compl. Ex. A at Ex. A); (2) a $15 per sample "processing and handling" fee (Compl. Ex. B); and (3) a $15 per sample "collection" fee. *Id*. Defendant's reference to the $15 amounts *billed* to Medicare for routine venipunctures is irrelevant. Mot. 5:7, fn.1. Medicare *pays* only $3 per draw, setting the fair value of the draw at $3, regardless of what Defendant and other labs submit as bills. Defendant's comparison to reimbursement for COVID-19 samples is an apples-to-oranges comparison. As Defendant concedes, the collection fee for COVID-19 samples incorporates the phlebotomist's travel time and costs. *See* Def's Req. for Judicial Not. In Supp. Mot. to Dismiss [ECF 59] ("RJN ISO MTD"), Ex. A (explaining the $23.46 reimbursement is for specimen collection from homebound and non-hospital patients and the $25.46 is for collection of samples from patients in skilled nursing facilities and non-hospital patients). In contrast, the samples collected in this case are done at a doctor's office. There is no travel time for the alleged phlebotomist to collect the patient samples since the patient has come to them.

Defendants in the *Berkeley Heartlab* case—a case Defendant tellingly fails to cite in its Motion—had the same argument properly rejected, attempting to disguise their illegality by calling them "P&H [packaging and handling] fees" instead of "draw fees," and telling employees and physicians "one word makes it legal the other illegal." *U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 500 (D.S.C. 2016) ("*Berkeley Heartlab I*"). The result should be the same here.

Defendant next attempts to distinguish its practices from the kickback schemes in the 2005 OIG Advisory Opinion. Defendant's argument misses the point. The OIG Advisory Opinion was primarily concerned with whether a per specimen payment for collecting and transporting blood samples to a lab can be an inducement to the physician to refer patients to the laboratory. The Advisory Opinion made clear: "Where a laboratory pays a referring physician to perform blood draws, particularly where the amount paid is more than the laboratory receives in Medicare reimbursement, an inference arises that the compensation is paid as an inducement to the physician to refer patients to the laboratory." RJN ISO MTD, Ex. B, p. 4. Although the specific facts may vary by laboratory as the government learns of these schemes, the underlying issue is whether "the Lab may be offering the blood draw remuneration to the physicians with the intent to induce new or continued referrals to the Lab." *Id.*

Defendant also attempts to distinguish its scheme from those in the 2014 Special Fraud Alert by incorrectly claiming the California Department of Public Health has condoned Defendant's practices. Mot. 6:16-28. In fact, the California Department of Public Health's "Important Notice Regarding Non-Compliance Inducements" (CDPH Notice) *confirms* the illegality of Defendant's scheme, consistent with the 2014 Special Fraud Alert and alleged in Relator's Complaint. Rather than laboratories "taking to heart" the OIG's warning, the CDPH Notice emphasizes that laboratories simply found new ways to try to disguise their illicit schemes. The CDPH Notice clarifies those schemes are still illegal. The CDPH Notice specifically identifies a scenario such as this one where a physician's staff member receives simultaneous payment from the physician and "directly from the laboratory as an independent contractor to the laboratory." RJN ISO MTD, Ex. D. The CDPH Notice

concludes the entire arrangement is an inducement, whether it results in the staff member being paid more or permits the physician to reduce the staff member's salary. *Id.*[10]

Throughout its argument, Defendant emphasizes its payments do not go directly to physicians, but to "independent contractor" phlebotomists. That distinction only makes Defendant's conduct *worse*, and is entirely divorced from the thrust of the Complaint. As described in the Complaint, Vibrant's "independent contractor" structure is a sham; an attempt by Defendant to mask its kickbacks from detection and allow physicians and their staff to supplement their income. Compl. ¶¶ 32, 34. Whether paid directly to a physician, or a physician's staff or family member, Defendant's "packaging and handling" and "collection" fees are remuneration and violate the AKS.

B. Defendant's capping and waiving patient co-payments and deductibles are remuneration that violate the AKS.

Vibrant next argues that because there *could be* legitimate reasons for waiving patient co-pay and deductible obligations, its practices could not have violated the AKS. However, as detailed above, under the AKS, a legitimate business purpose will not legitimize a payment if there is also an illegal purpose, *i.e.*, inducing referrals. OIG Supplemental Compliance Program Guidance; *see U.S. ex rel. Bartlett v. Ascroft,* 39 F. Supp. 3d 654, 677 (W.D. Pa. 2014); *see also Crescendo*, 2020 WL 2614959 at *7 (quoting same). The test for whether the waiver of a copay or deductible constitutes remuneration is whether the complaint alleged at least one of the purposes of the waiver was to induce patient referrals. *Berkeley Heartlab I,* 225 F. Supp. 3d at 499 fn. 3, *citing U.S. ex rel. Sharp v. E. Okla. Orthopedic Ctr.*, No. 05-CV-572-TCK-TLW, 2009 WL 499375, at *25 (N.D. Okla. Feb. 27, 2009); *see also Kats*, 871 F.2d at 108 (9th Cir. 1989) (agreeing "the Medicare fraud statute is violated if 'one purpose of the payment was to induce future referrals'" (quoting *United States v. Greber*, 760 F.2d 68, 69 (3d Cir.1985))). Relator's Complaint does this. Compl. ¶ 5.

[10] Defendant also attempts to distinguish its scheme from the 1994 OIG Special Fraud Alert by focusing on a narrow and irrelevant factual difference about what services the phlebotomist performs. Mot. 7:1-18. The 1994 OIG Special Fraud Alert, however, is cited in the Complaint with respect to Defendant's policy of routinely capping and waiving patient copayments and deductibles, not phlebotomy services. Compl. ¶ 43. Nor can Defendant credibly argue its practices are carved out because the phlebotomist is "placed" in the physician's office by Vibrant. *See*, RJN ISO MTD, Ex. C. As alleged in the Complaint, the person doing the blood draw is an existing staff or family member of the physician. Compl. ¶¶ 32, 34.

Defendant ignores this caselaw and claims the waivers are legitimate. However, throughout the medical industry it is well known waivers of copayments or deductibles are valuable remuneration for referring physicians. The 1994 OIG Special Fraud Alert cited laboratories' waiver of charges to providers for lab tests, such as copayments, as an example of illegal kickbacks. Compl. ¶ 43; RJN ISO MTD Ex. D. The specific question addressed by the OIG in that alert was whether waivers of managed care payments were improper. However, the OIG explained the payments were improper not because it was a managed care patient or government funded payer, but instead because promising a physician their patients will not be charged a co-pay is a thing of value. The fact the OIG specifically considered managed care, not all insurance, is a distinction without a difference in this context.

Defendant's protestations that its waiver scheme is legitimate are misplaced. Not only is this a factual issue not appropriate for resolution in this motion, it ignores Relator's allegations of the scheme being a company policy, and a marketing tool. Compl. ¶¶ 45, 48. Defendant's waiver scheme provides remuneration and violates the AKS.

C. Relator's Complaint meets the requirements of Rule 9(b).

Defendant next argues the Complaint fails under Rule 9(b) because it does not detail every aspect of Defendant's fraudulent schemes, including every person involved, every potential payer, every physician it contracted with, the referred business it received as a result of it kickbacks, and the precise time frame of its schemes. Mot. 12:2-16:20. These details are either unnecessary or sufficiently alleged in Relator's Complaint.

Defendant's argument tellingly ignores the most recent guidance from the Ninth Circuit on pleading FCA claims: *United States ex rel. Swoben v. United Healthcare Ins. Co.*, 848 F.3d 1161 (9th Cir. 2016). In *Swoben*, the Ninth Circuit explained Rule 9(b) "'does not require absolute particularity or a recital of the evidence,' … , a complaint need not allege 'a precise time frame,' 'describe in detail a single specific transaction' or identify the 'precise method' used to carry out the fraud, … . The complaint also need not 'identify representative examples of false claims to support every allegation.'" *Id*. at 1180 (citations omitted). *Swoben* is especially helpful because it provides two specific examples—with block quotes from the relator's complaint—of allegations that pass muster under Rule 9(b); and three specific examples of allegations that do not. *See id.* at 1181-82. The Ninth

Circuit in *Swoben* thus provided solid templates against which to assess other complaints under the FCA.

The allegations of Relator's Complaint meet, and exceed, the level of specificity the Ninth Circuit found adequate in *Swoben*. As summarized below, the Complaint describes "with particularity the circumstances constituting fraud," including alleging "the who, what, when, where, and how of the misconduct charged." *Id.* (quoting *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010)).

1. Relator alleges Defendant's packaging fee scheme with sufficient detail.

Relator's Complaint sufficiently details how Defendant perpetrated its fraudulent packaging fee scheme, including:

- ***What*** the terms of Vibrant's sham Phlebotomy Services Contracts (PSC) and Phlebotomy Services Agreements (PSA) are with referring physicians for "packaging and handling" and "collection" fees (Compl. ¶¶ 32, 36-37, Exs. A-B);
- ***Who*** signs the PSCs, PSAs and kickback checks for Vibrant: Vibrant's Chief Operating Officer Vasanth Jayaraman (Compl. Exs. A-C);
- ***How*** referring physicians submit samples for kickbacks under the PSCs and PSAs: through "monthly log list, invoice or statement:" (Compl. ¶¶ 32, 37, Exs. A-B);
- ***What*** is included on the monthly log list: "the names and date of birth of each patient, ordering provider and the date when each specimen was collected" (Compl. Ex. B);
- ***Where*** the monthly log list is submitted: to Vibrant's "labservices@vibrant-america.com" email account (*id.*);[11]
- ***When*** Vibrant pays the kickbacks: "the last day of the month" (*id.*);
- ***How*** to connect the kickback checks to the phlebotomy services: through the "monthly log list, invoice or statement" (*see id.*); and

[11] *See Boston Heart,* 332 F. Supp. 3d at 77 (D.D.C. 2018) (explaining relator sufficiently pleads the "where" requirement of Rule 9(b) where he alleges the conduits and locations through which the scheme allegedly occurred).

- ***Why*** Defendant's $15 payments per specimen—which is five-times Medicare's published reimbursement rate—exceed fair market value and induce physicians to refer business to Vibrant (*see id.*).

In the face of these details, Defendant makes several redundant and meritless arguments.

a. Defendant's sham phlebotomist payments are remuneration to referring physicians.

As detailed above, Defendant's packaging fee payments under its sham phlebotomist contracts are remuneration to the referring physician. Through these prohibited kickbacks, physicians can subsidize their staff's income or pad their own pockets. In the specific instance detailed by Relator, the referring physician was able to supplement their income by directing Defendant's kickbacks to a family member, someone who is not licensed as a phlebotomist. Compl. ¶¶ 32-34. This is a thing of value to the physicians, *i.e.*, remuneration. Defendant takes umbrage with these allegations, complaining Relator protected that individual's privacy in providing redacted copies of their sham agreement. Mot. 11:2-10. But those are *Defendant's* documents and contain sufficient detail for Defendant to look up the unredacted versions in their own records. Moreover, those same documents—in unredacted form—along with other documents identifying Relator's members have now been produced in discovery. Far from making conclusory or unsubstantiated allegations, Relator supported its allegations with direct evidence, including both the sham agreements and a kickback check received by a referring physician's spouse. Compl. Exs. A-C.

b. Payments to phlebotomists are inducements.

Defendant next argues Relator must identify a physician who received and referred business that resulted from a kickback. Mot. 12:2-22. This is not the standard. Relator does not need to "describe in detail a single specific transaction." *See Swoben*, 848 F.3d at 1180. Relator's description of the precise manner in which Defendant carries out its packaging fee scheme is sufficient to protect against false or unsubstantiated charges and gives Defendant adequate notice for it to prepare a responsive pleading. *See id.* Moreover, as noted above, Relator does provide specific examples and direct evidence supporting its allegations.

For these reasons, Magistrate Judge Hixson rejected the identical argument in *Crescendo*:

> Contrary to Defendants' assertion, STF has alleged great detail concerning the alleged processing fees scheme. True, it hasn't alleged any particular transaction or named a particular physician who sent samples to Crescendo, but it doesn't need to allege a precise time frame or describe in detail a specific transaction, as long as it alleges details of the scheme sufficient enough to '"give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge...."' " *United Healthcare*, 848 F.3d at 1180 (quoting *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (discussing Rule 9(b) in the context of an FCA claim)). It has done that.

Crescendo, 2020 WL 2614959, at *9.

Relying on *U.S. ex rel. Gough v. Eastwestproto, Inc.*, No. CV-14-465 DMG, 2018 WL 6929332 (C.D. Cal. Oct. 24, 2018), Defendant next argues there is no explicit allegation of a *quid pro quo*. *Gough* concerned an ambulance company's alleged "cash for calls" kickback scheme and providing of various gifts where relators relied exclusively on an overheard conversation about the "cash for calls" scheme and a vague email about providing gifts to hospitals to support their allegations. *Id.* at *6, *8. The court granted the motion to dismiss because the complaint lacked reliable details, and simply did not describe the practices with adequate clarity. *Id.* at *6-*7, *10.

Unlike in *Gough*, the practices at issue here are described with sufficient detail and with supporting evidence. Indeed, Vibrant does not even seriously contest that it engaged in the practices—but only disputes whether those practices violated the AKS or were done with the requisite scienter. Defendant certainly has been given sufficient notice of its misconduct to defend itself. *Crescendo*, 2020 WL 2614959 at *9 (quoting *Swoben*, 848 F.3d at 1180).

Vibrant next argues the Complaint fails to identify any tests that resulted from the scheme that were not "reasonable nor necessary." Mot. 12:27-13:8. Vibrant misses the mark. Unnecessary services are not an element of an AKS violation. Indeed, the AKS is built around a presumption that kickbacks lead to tainted medical judgment and the ordering of unnecessary tests. OIG Advisory Opinion No. 05-08 at p. 4; *see also,* Compl. ¶ 41.

Finally, Vibrant repeats its meritless fair market value argument (Mot. 13:9-13), which both misstates the legal standard and ignores the allegations of the Complaint, as discussed *supra*.

2. Relator alleges Defendant's waiver scheme with sufficient detail.

Relator's Complaint also alleges the requisite details of Defendant's waiver scheme, including:

- ***What*** the terms of the agreement were – promises to physicians that Vibrant would cap patient copayments or deductibles at $25 or waive them entirely in exchange for physicians referring business to Defendant (*See* Compl. ¶¶ 45-49);
- ***Who*** was involved, including a specific example involving Tanja Elliot and a physician (*id.* at ¶ 48)
- ***When*** Defendant pitched its policy to a referring physician: April 2016 (*id.*); and
- ***How*** this remuneration benefits physicians (*see id.* at ¶ 43).

Defendant erroneously relies on a different case filed by Mr. Riedel against a different laboratory defendant for different violations of anti-kickback laws and Georgia's state false claims statute: *Georgia ex rel. Hunter Labs. v. Lab. Corp. of Am.*, No. 1:13-cv1838-SCJ, 2015 WL 12591797 (N.D. Ga. May 19, 2015). Mot. 20:18-28. However, that case involved below-cost testing as an inducement to physicians, not waivers of patient payment obligations.[12]

a. Copayment and deductible caps and waivers are remuneration to referring physicians.

Relying solely on *United States v. Chang*, No. CV133772DMGMRWX, 2017 WL 10544289 (C.D. Cal. July 25, 2017), Defendant next argues waivers cannot be renumeration because the patient, not the physician, receives the benefit. But *Chang* stands in stark contrast to several other published cases, OIG guidance, and Magistrate Judge Hixon's recent decision in *Crescendo*.

As Magistrate Judge Hixson explained:

> Defendants make much of the fact that STF does not explicitly draw the line from Crescendo waiving co-pays or deductibles to physicians referring patients. "[STF] presupposes a link," they argue, "and in doing so, asks the Court to fill the gap." Mem. at 18. **But the gap is not a large one to fill: no patient likes additional costs; if a lab waives patients' fees and commits to not referring patients to collections, thus allowing physicians to "reassure their patients that they will not be responsible for more than $25," that is something of value to physicians and they might be induced to send more patients to that lab (especially when the lab is paying $15 per sample to boot).** *See Bos. Heart*, 332 F. Supp. 3d at 66 (allegation sufficiently alleged how "purported waiver practice provided value to physicians; namely, by saving their time not spent on explaining co-payment and

[12] That case was remanded to state court for determination of the other legal theories, as they were state law theories and the federal court determined it lacked subject matter jurisdiction over the claims. In companion cases filed in various states around the country, including Massachusetts, California, Virginia, Nevada, Florida and Michigan, the various defendants *paid over $315 million in settlements*.

> deductible charges to patients and providing them an opportunity to market free laboratory testing").

Crescendo, 2020 WL 2614959 at *10 (emphasis added).

As explained in *Berkeley Heartlab I*:

> Defendant Berkeley argues that the waiver of copays and deductibles does not constitute remuneration within the context of the AKS – and therefore cannot be the basis for an FCA violation – because there is no allegation that physicians make any payments to labs for tests to be performed. However, the appropriate test for whether the waiver of a copay constitutes remuneration is whether the complaint has alleged that at least one of the purposes of the waiver was to induce patient referrals. The complaint satisfies that requirement by alleging that Berkeley waived copays with the intent to induce physician referrals.

Berkeley Heartlab I, 225 F. Supp. 3d at 499, fn. 3, citations and quotations omitted; *see also U.S. ex rel. Lutz v. Berkeley Heartlab, Inc.*, 247 F. Supp. 3d 724, 730-32, 734 (D.S.C. 2017) ("*Berkeley Heartlab II*").

And in *Boston Heart*:

> In this case, the relator alleges that Boston Heart waives physicians' privately insured patients' co-payments and deductibles, "so long as the physicians send all of their lipid-related business—especially the highly profitable Medicare business—to [Boston Heart]." In the Court's view, this allegation, if true, would also implicate the Anti-Kickback Statute because it would constitute the provision of free services, i.e., the waiver of co-payments and deductibles, that result in a benefit to the provider, i.e., by saving the physicians' time not spent on explaining co-payment and deductible charges to patients and providing them an opportunity to market free laboratory testing. And, the relator alleges that the objective of Boston Heart's waiver of co-payments and deductibles scheme is to gain additional Medicare business, which in turn results in federal funds being acquired by Boston Heart as a result of its fraudulent kickback scheme. Accordingly, Boston Heart's argument that the relator fails to plausibly allege inducement because the 1994 OIG Special Fraud Alert does not specifically reference privately insured patients fails. Therefore, the Court finds that the relator sufficiently alleges that Boston Heart's waiver of patients' co-payments and deductibles constitutes a kickback, and therefore, sufficiently alleges the falsity element of a false presentment claim under the False Claims Act.

United States ex rel. Riedel v. Boston Heart Diagnostics Corp., 332 F. Supp. 3d 48, 67–68 (D.D.C. 2018) (citations omitted).

As in *Crescendo*, *Berkeley Heartlab I*, and *Boston Heart*, Relator alleges that the waiver of co-pays and deductibles is of value to physicians, and that one purpose of Defendant's waiver scheme is to induce physicians' referral of additional business, especially government pay business. Compl. ¶ 49. Accordingly, Vibrant's scheme provides physicians with unlawful remuneration.

b. Copayment and deductible caps and waivers are inducements.

Defendant next argues Realtor's Complaint does not plead any instance of a Vibrant employee telling a physician their patients' copayments or deductibles would be capped or waived in exchange for referral of business. Mot. 15:17-22.

Defendant ignores Relator's specific allegation that—knowing the scheme is illegal—Vibrant does not list the policy on its website, but instead explains it verbally to physicians, as a marketing tactic. For example, Vibrant's sale representative, Tanja Elliott, told a southern California physician about Vibrant's waiver policy in April 2016. Compl. ¶ 48. Vibrant pitches this scheme knowing it provides a benefit to the physician. *See id*. ¶ 49.

Defendant also argues Relator must identify specific examples of false claims, including claims that resulted in "pull through" Medicare and Medicaid business. Mot. 15:23-16:11. However, the Ninth Circuit expressly rejected requiring a relator to "identify representative examples of false claims to support every allegation." *Ebeid*, 616 F.3d at 998; *see also United States ex rel. Silingo v. WellPoint, Inc.*, 904 F.3d 667, 678-79 (9th Cir. 2018) ("We do not require the complaint to identify representative examples of actual false claims, though that is one way to satisfy the heightened pleading standard."); *Swoben*, 848 F.3d at 1180 (same).

Instead, "it is sufficient to allege 'particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Swoben*, 848 F.3d at 1180 (quoting *Ebeid* at 998-99). Moreover, "the requirements of Rule 9(b) relax 'as to matters peculiarly within the opposing party's knowledge.'" *Wool v. Tandem Computers, Inc.*, 818 F.2d 1433, 1439 (9th Cir. 1987) (quoting case); *see also U.S. ex rel. Vatan v. QTC Med. Servs., Inc.*, 721 F. App'x 662, 663–64 (9th Cir. 2018) (explaining a "requirement to the contrary would vitiate the False Claims Act, by excluding many whistle-blowers who—as here—allege insider knowledge of wrongdoing that few others would be positioned to reveal and solely lack access to the corporate documents outlining the precise nature of the company's obligations."). Relator's Complaint meets this standard. Relator is not in a position to identify actual claims Defendant submitted for payment and is not required to do so at this stage. Thus, Relator's allegations regarding Defendant's waiver scheme satisfy Rule 9(b).

3. The Complaint provides reliable indicia of claims submission.

In a concluding paragraph, Vibrant argues Relator's Complaint fails to provide "reliable indicia" that false claims were submitted. Mot. 16:13-20. Defendant's "argument," however, is an irrelevant attack on Relator not being an "insider."

Relator's relationship to the Defendant is immaterial to showing "reliable indicia" Defendant submitted false claims. "A complaint provides the requisite indicia of reliability where 'specific allegations of the defendant's fraudulent conduct necessarily [lead] to the plausible inference that false claims were presented to the government.'" *Berkeley Heartlab II*, 247 F. Supp. 3d at 729 (quoting *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F. 3d 451, 457 (4th Cir. 2013)). As detailed above, Relator specifically alleges Defendant's fraudulent conduct through its packaging fee and waiver schemes. Moreover, Relator demonstrated a "concrete connection to the alleged schemes" by providing direct evidence of the schemes.

Every blood sample the Defendant obtained through a kickback—be it a $15 "packaging" or "collection" fee or a capped or waived copayment—is tainted and therefore violates 31 U.S.C. § 3729(a)(1)(A); *see* 42 U.S.C.A. § 1320a-7b ("a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the federal False Claims Act]."); *U.S. ex rel. Banigan v. Organon USA Inc.*, No. CV 07-12153-RWZ, 2016 WL 10704126, at *5 (D. Mass. Aug. 23, 2016) ("By enshrining their distaste for kickbacks in statutes and provider agreements, these states have made plain their unwillingness to pay kick-back tainted claims."). Relator is not obligated to identify specific referrals where, as here, it details how Defendant's fraudulent schemes taint every claim submitted to Medicare, Tricare, Medi-Cal or private insurers. *Ebeid*, 616 F. 3d at 998-99 (9th Cir. 2010).

Moreover, Defendant's argument requires an absurd inference in its favor: that it ran lab tests on samples it paid for but never submitted claims for payment; *i.e.*, that it ran free tests. Defendant offers no explanation for why it would pay a phlebotomist for collecting tests, run them, but not seek reimbursement for them. Accordingly, the only plausible inference is that alleged in the Complaint: that Vibrant paid for the tests in order to submit reimbursement claims to public and private insurers for processing them. Compl. ¶¶ 42, 49, 6; *see Starr*, 652 F.3d at 1216 ("If there are two alternative

explanations, one advanced by defendant and the other advanced by plaintiff, both of which are plausible, plaintiff's complaint survives a motion to dismiss under Rule 12(b)(6).").

D. The Complaint adequately alleges materiality as AKS violations are always material.

Citing *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1995-96 (2016), Defendant argues Relator's Complaint fails to allege materiality. Mot. 16:21-17:16. The materiality requirement described in *Escobar*, however, only becomes an issue in "implied certification" cases. This is not an implied certification case—indeed, it is not a "false certification" case at all, because "certification" is not required to establish liability when the defendant has engaged in an illegal kickback scheme.

Both "express" and "implied" certification are merely ways to establish a "legally" false claim. *See, e.g.*, *Silingo*, 904 F.3d at 675 ("There are two cognizable theories of liability for legally false claims: express false certification and implied false certification."). In 2010, Congress amended the AKS to state expressly that claims that arise from its violation constitute false claims under the FCA. *See* 42 U.S.C. 1320a–7b(g) ("[A] claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of [the FCA.]"). In other words, claims resulting from violation of the AKS constitute "legally" false claims. As such, Relator need not allege "certification" to establish a claim under the FCA when the defendant is alleged to have violated the AKS. *See*, *e.g.*, *U.S. ex rel. Wood v. Allergan, Inc*., 246 F. Supp. 3d 772, 812–13 (S.D.N.Y. 2017) (the express language of the AKS "makes plain" that claims premised on an underlying violation of the AKS are "clearly legally sufficient" false claims under the FCA); *see also United States v. Rogan*, 517 F.3d 449, 452–53 (7th Cir. 2008) (all claims submitted by defendant were false because they were acquired by kickback); *see also U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 386 (4th Cir. 2015) (defendant was "knowingly asking the government to pay an amount that, by law, it could not pay" for claims tainted by violation of analogous Stark Law).[13]

[13] Defendant relies on *Knudsen v. Sprint Commc'ns. Co.*, No. C1304476 CRB, 2016 WL 4548294 (N.D. Cal. Sep. 1, 2016) and *U.S. ex rel. Durkin v. Cty. of San Diego*, 300 F. Supp. 3d 1107 (S.D. Cal. Jan. 11, 2018). However, those cases did not involve violations of the AKS. *Knudsen* and *Durkin* are

In any event, the materiality standard of *Escobar* is easily met here. *Escobar* held that materiality can be satisfied by showing either: (1) "a reasonable man would attach importance to [the misrepresented information] in determining his choice of action in the transaction"; or (2) "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not." *Escobar*, 136 S. Ct. at 2002-03 (quoting the Restatement (Second) of Torts § 538, at 80). Given the Congressional mandate reflected in the Anti-Kickback Statutes, there can be no dispute that Medicare attaches importance to AKS violations. Thus, Relator alleges materiality.

E. The Complaint adequately alleges Defendant's scienter.

Defendant next argues Relator's Complaint fails to adequately allege Defendant "knowingly" perpetuated its illicit schemes. Defendant claims it could not have been acting "knowingly" because it believed it was acting lawfully. Mot. 18:14-20. Defendant's argument misstates the law and is, at best, grossly premature.

Under Rule 9(b), "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." The Ninth Circuit has interpreted this to mean "plaintiffs may aver scienter generally, just as the rule states—that is, simply by saying that scienter existed." *In re GlenFed Inc. Sec. Litig.*, 42 F.3d 1541, 1547 (9th Cir. 1994) (*en banc*). "Because Rule 9(b) permits knowledge to be pled generally, there is no basis for dismissal for failure to plead knowledge with particularity." *Boston Heart*, 255 F. Supp. 3d at 29, quoting *United States v. Honeywell Int'l, Inc.*, 798 F. Supp. 2d 12, 22 (D.D.C. 2011).

"Proving the scienter element under the FCA requires 'no proof of specific intent to defraud.'" *Crescendo*, 2020 WL 2614959 at *9 (quoting 31 U.S.C. § 3729(b)(1)(B)). To prove a claim under the FCA premised on a violation of the AKS, defendant's conduct "must have been made 'knowingly,' which can be proven by actual knowledge, deliberate ignorance, or reckless disregard." *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 167 (D.D.C. 2008); 31 U.S.C. § 3729(b)(1)(A). And Relator need only allege "'facts supporting a plausible inference of scienter.'"

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both implied certification cases based on violations of contractual agreements. *Knudsen,* 2016 WL 4548294 at *3; *Durkin,* 300 F. Supp. 3d at 1114. As such, they are not relevant here.

Crescendo, 2020 WL 2614959 at *9 (quoting *Winter ex rel. U.S. v. Gardens Reg'l Hosp. & Med. Ctr., Inc.,* 953 F.3d 1108, 1122 (9th Cir. 2020). Relator's Complaint more than does so.

In the *Berkeley Heartlab* cases, several relators filed FCA actions against various clinical testing labs for paying packaging fees of $15 and by waiving co-pays and deductibles, among other fraudulent schemes. The defendants tried to distance themselves from "knowingly" paying illegal draw fees by labeling them "packaging and handling" fees. *Berkeley Heartlab I*, 225 F. Supp. 3d at 500. In denying motions to dismiss, the court explained the "Defendants knew of the illegality of the P&H fees and tried to disguise them by calling them P&H fees instead of draw fees . . . ." *Id.* at 500.

Similarly, in *Crescendo*, the defendants contracted to pay physicians $15 "processing" fees for each specimen sent to their laboratory. 2020 WL 2614959 at *7. Relator alleged defendants described these fees as "fair market value" in their sham contracts to disguise their illegality. *Id*. Rejecting the same argument Defendant makes here and finding relator sufficiently alleged scienter, Magistrate Judge Hixson agreed the allegation inferred "Defendants knew their practice was prohibited renumeration and were trying to stay one step ahead of the string of successful cases holding other laboratories responsible for the same conduct." *Id*.

Here, like the defendants in *Berkeley Heartlab I* and *Crescendo*, Vibrant's rebranding of its draw fees as "packaging and handling" and "collection" fees demonstrates Defendant knew its scheme was illegal and was attempting to disguise its conduct. Worse, Defendant's sales representative encouraged a referring physician to have a family member with a different surname sign the sham phlebotomist agreements to not "raise suspicions." Compl. ¶ 33. Defendant knew its scheme was prohibited and actively tried to hide it.

Relator also alleges Defendant knew its waiver scheme was prohibited and endeavored to keep the policy secret by not publishing it, only allowing sales representatives to pitch it verbally to referring physicians. *See id*. ¶ 48. This reflects a consciousness of guilt. Similar to the defendants in the *Berkeley Heartlab* and *Crescendo* cases, these facts lead to the inference Defendant knew its conduct was prohibited and attempted to conceal it.

Thus, Relator adequately alleges Defendant's scienter for both fraudulent schemes.

F. The Complaint adequately alleges violations of the California False Claims Act.

Defendant contends Relator's claims under the California False Claims Act are deficient for the same reasons as under the FCA. For the same reasons discussed above, Relator's CFCA claims are sufficient.

G. The Complaint adequately alleges violations of the California Insurance Fraud Prevention Act.

Defendant argues Relator's claims under CIFPA fail because Relator is not an "interested person" under the statute. Mot. 20:2-21:9. Defendant also argues Relator's CIFPA claims fail to meet Rule 9(b) requirements. Mot. 21:10-24. Both arguments should be rejected.

1. Relator is an "interested person" under a plain reading of the CIFPA.

Relator is an "interested person" with standing under the CIFPA. Defendant's argument relies on a South Carolina trial court decision in *United States v. Laboratory Corp. of Am.*, No. 9:14-CV-3699-RMG, 2019 WL 236799 (D.S.C. Jan. 16, 2019) ("*Lutz*"). Crucially, Defendant omits the *Lutz* court's caution that it did "not seek to define for California . . . the contours of who qualifies as an 'interested person.'" *Lutz* at *5.

Neither the CIFPA nor the FCA limit relators to only those individuals "connected" to a defendant. Such an overly narrow interpretation of an "interested party" frustrates the intent of the statute by excluding persons with information about fraudulent conduct to sue simply because they have a tangential relationship to the party engaging in fraud.

Like the FCA, CIFPA's objectives are to assist state and local governments to identify, investigate and prosecute fraud in the health insurance industry where such fraud "causes losses in premium dollars and increases in health care costs unnecessarily." Cal. Ins. C. § 1871(a), (h); *People ex rel. Allstate Ins. Co. v. Weitzman*, 107 Cal. App. 4th 534, 544 (Cal. Ct. App.), as modified on denial of reh'g (Apr. 24, 2003) (explaining the goals of the 1986 amendments to the FCA were "to encourage those with information about fraud . . . to bring it into the public domain" and "assist and prod the government into taking action"). To accomplish this, "any interested person" can file a civil action on behalf of themselves and the State, similar to a private "relator" who brings a *qui tam* action under the

FCA. Cal. Ins. C. § 1871.1(e)(1); 31 U.S.C. § 3730(b).[14] Neither CIFPA nor the FCA requires a relator be connected to a defendant as an employee, insurer, client, or affected by or involved in Defendant's fraudulent schemes. Indeed, *qui tam* relators "can be anyone." *Avco Corp. v. U.S. Dep't of Justice*, 884 F.2d 621, 627 (D.C. Cir. 1989).

Nevertheless, far from being unconnected, Relator's specific allegations and supporting documents demonstrate Relator is "connected" to Vibrant under the *Lutz* criteria. Relator supplied details of specific contacts with Defendant, including: (1) conversations with Defendant's sales representatives (Compl. ¶¶ 33, 48); (2) Defendant's sham phlebotomy contracts demonstrating "employment:" (3) Defendant's kickback checks received (*id*. ¶¶ 36-38, Exs. A-C) demonstrating involvement in the submission of tainted insurance claims; and (4) Defendant's own requisition form (Compl. ¶ 46, Ex. E). Drawing all inferences in Relator's favor, Relator sufficiently alleges a "connection" to Defendant and is therefore an "interested person" under the CIFPA.

2. The Complaint adequately states a claim for violation of the CIFPA under Rule 9(b).

For the same reasons discussed above, each of Defendant's arguments regarding the adequacy of Relator's CIFPA allegations should be rejected as well. Relator's Complaint alleges: (1) the details of how each of Defendant's fraudulent schemes were perpetrated; (2) that these fraudulent schemes tainted Defendant's claims to insurers; and (3) private insurance companies were harmed as a result of Defendant's schemes. This is sufficient.

Defendant again attempts to make inappropriate factual arguments at this stage. Relator is not required to allege facts sufficient to eliminate all potential purposes for Defendant's conduct. Like the AKS, violations of Cal. Ins. Code § 1871.7(a) occur when (1) Defendant provides or promises an item or service of value to a physician and (2) a purpose of Defendant providing such item or service is to influence the physician to refer business to defendant. *State ex rel. Wilson v. Super. Ct.*, 227 Cal. App. 4th 579, 593 (Cal. Ct. App. 2014).

[14] "Interested parties" in CIFPA actions are described as "relators" and the lawsuits actions are known as "*qui tam* actions" exactly like claims under the FCA. *Weitzman*, 107 Cal. App. 4th at 538.

G. The policies underlying Rule 9(b) are met.

In its final sections, Defendant repeats its legally and factually deficient arguments under the guise of policy discussion, sprinkling in attacks of Mr. Riedel, a manager of Relator STF, LLC, as a "serial relator." Mot. 23:2. These unwarranted and irrelevant *ad hominem* attacks improperly assume Mr. Riedel is Relator's sole member, when the Complaint states the opposite. Compl. ¶ 10 ("members are involved in the healthcare industry"). Moreover, Defendant fails to explain why prosecuting other successful false claims suits makes Mr. Riedel an improper plaintiff. Through successful FCA actions against multiple medical laboratories, Mr. Riedel has recovered hundreds of millions of dollars for taxpayers. Indeed, Mr. Riedel's success in other FCA cases cuts against Defendant's transparent claims they did not know their conduct was illegal. Far from being frivolous or parroted allegations, Relator's allegations against Defendant are but another example of a laboratory company bilking the health care system. The actions of Relator's members, including Mr. Riedel, should be recognized as important and necessary, not villainized and baselessly criticized as seeking personal profit.

The Complaint meets, and exceeds, the Rule 9(b) standards, and satisfies its underlying policies. *See U.S. ex rel. Swoben v. United Healthcare Ins. Co*., 848 F.3d 1161, 1180 (9th Cir. 2016). Again, Defendant does not even seriously contest that it engaged in the practices described in the Complaint. The only dispute—which is premature at this stage—is whether Defendant designed those practices with an intent to induce referrals. Accordingly, Defendant cannot argue that it fails to understand the scheme alleged, or that the practices actually occurred. The purposes of Rule 9(b) are fulfilled.

V. CONCLUSION

For the foregoing reasons, Relator respectfully requests Defendant's Motion to Dismiss be denied. To the extent the Court grants Defendant's Motion, Relator respectfully requests leave to file an amended complaint.

Dated: June 15, 2020

COTCHETT, PITRE & McCARTHY, LLP

By: */s/ Mallory A. Barr*
JUSTIN T. BERGER
MALLORY A. BARR

Attorneys for Relator STF, LLC